filed, the witness (and his or her attorney), upon proper identification, shall have the right to inspect the official transcript of the witness' own testimony. If such a petition is denied by the General Counsel, he shall inform the petitioner of the right to inspect the transcript.

(c) Good cause for denying a witness' petition to procure a transcript of his or her testimony may include, but shall not be limited to, the protection of: trade secrets and confidential business information contained in the testimony, security-sensitive operational and vulnerability information, and the integrity of Board investigations.

Dated: December 2, 2002.

Christopher W. Warner,

General Counsel.

[FR Doc. 02–30981 Filed 12–6–02; 8:45 am]

BILLING CODE 6350–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

Solicitation of Public Comments on Exceptions Under Section 1128A(a)(5) of the Social Security Act

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice of intent to develop regulations.

SUMMARY: The OIG is soliciting public comments on the possible development of exceptions under section 1128A(a)(5) of the Social Security Act (the Act), the civil money penalty (CMP) prohibition on offering inducements to Medicare and Medicaid beneficiaries to influence their selection of a provider, practitioner, or supplier. In particular, the OIG is interested in comments on possible exceptions for complimentary local transportation, inducements related to clinical trials, and inducements of nominal value. The OIG welcomes suggestions for other exceptions under section 1128A(a)(5) of the Act, as well.

DATES: To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on February 7, 2003.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–72–N, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG–72–N. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, (202) 619–0089, OIG Regulations Officer

SUPPLEMENTARY INFORMATION:

I. Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, amended the Social Security Act (the Act) to prohibit providers from offering patients any inducement to order or receive Medicare or Medicaid reimbursable items or services from a particular provider, practitioner, or supplier. Specifically, section 231(h) of HIPAA established a new provision, section 1128A(a)(5) of the Act, to provide for the imposition of a CMP against any person who:

> Offers or transfers remuneration to any individual eligible for benefits under [Medicare or Medicaid] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [Medicare or Medicaid].

Section 231(h) of HIPAA also created a new section 1128A(i)(6) of the Act to define ''remuneration'' for purposes of section 1128A(a)(5) of the Act. This section defines ''remuneration,'' in relevant part, as ''transfers of items or services for free or for other than fair market value.'' Remuneration does not include certain enumerated practices, including waivers of coinsurance and deductible amounts if the waiver is not advertised; not routinely offered; and made following an individualized good faith assessment of financial need or after the failure of reasonable collection efforts. Other statutory exceptions include properly disclosed copayment differentials in health plans; incentives to promote the delivery of preventive health care services; any practice permitted under a safe harbor to the federal anti-kickback statute at 42 CFR 1001.952; and waivers of hospital outpatient copayment amounts in excess of the minimum copayment amounts.

In 1998, Congress enacted section 6201 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999, which authorized the Secretary to issue regulations establishing ''safe harbor'' exceptions under section 1128A(a)(5) of the Act for payment practices that would otherwise run afoul of the statute. In addition, the Secretary is vested with the authority to issue advisory opinions providing legal and regulatory guidance to providers under this section.

The OIG issued proposed regulations interpreting section 1128A(a)(5) of the Act on March 25, 1998 (63 FR 14393) and final regulations on April 26, 2000 (65 FR 24400). To alert the industry to the scope of acceptable practices, promote compliance, and level the competitive playing field, we have issued further guidance on the statute in a Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries (67 FR 55855; August 30, 2002). In the Bulletin, we indicated our intent to solicit public comments on the possible regulatory exceptions to the statute.

II. Solicitation of Comments and Suggestions for Additional Exceptions

The OIG invites comments and suggestions for new regulatory exceptions to section 1128A(a)(5) of the Act. In particular, we are seeking comments and suggestions on possible exceptions for complimentary local transportation; remuneration to induce participation in clinical trials; and inducements of low value. We also welcome comments on other possible exceptions to section 1128A(a)(5). Comments that include detailed descriptions of relevant industry business practices, address the legal and policy concerns raised by the application of section 1128A(a)(5) to particular business practices, and offer specific suggestions for applicable criteria that might apply under a regulatory exception are particularly useful.

A. Criteria for Establishing Exceptions

In giving the OIG authority to create additional regulatory exceptions to—and issue advisory opinions on—section 1128A(a)(5) of the Act, Congress provided no guidance on the criteria to be applied. The absence of criteria is especially problematic because any exception to the prohibition creates the very harm prohibited (*i.e.*, the inducement of beneficiaries), resulting in an uneven competitive playing field. Moreover, any exception will result in a valuable benefit to Medicare and

Medicaid beneficiaries. In the absence of statutory guidance, attempting to distinguish among types of benefits or categories of beneficiaries necessarily results in arbitrary standards. In these circumstances, the OIG has determined to exercise its regulatory authority cautiously by limiting exceptions to areas in which Congress has indicated a desire for flexibility in the provision remuneration to beneficiaries or where the provision of such remuneration serves a governmental interest.

B. Specific Areas of Interest

1. Complimentary Local Transportation

In enacting section 1128A(a)(5) of the Act, Congress intended that the statute not preclude the provision of complimentary local transportation of nominal value (H.R. Conf. Rep. No. 104–191 at 255 (1996)). We have interpreted nominal value to mean no more than $10 per item or service or $50 in the aggregate. (*See* 65 FR 24411; April 6, 2000.) We are concerned that this interpretation may be overly restrictive in the context of complimentary local transportation. Accordingly, we seek public input on the following issues as they relate to a possible exception for complimentary transportation:

• *Forms of transportation.* What forms of transportation should be considered in developing an exception and how should various forms of transportation be treated? We believe that luxury transportation (*e.g.*, limousines), as well as certain specialized transportation (*e.g.*, ambulances) should not be covered in an exception. Are there other forms of transportation that should be excluded (*e.g.*, handicapped-accessible vans, taxis, public transportation)?

• *Area in which transportation is offered.* Should the complimentary transportation service be limited to a provider's primary service area? If so, how should a service area be defined? Should there be a different rule for rural or underserved areas or patients? Should complimentary transportation be permitted to the nearest facility even if the patient resides outside the primary service area?

• *Eligibility for transportation.* Should providers be required to offer the transportation services to all patients? What other kinds of eligibility requirements might be permitted? Certain eligibility criteria, such as diagnosis or insurance coverage, would clearly raise significant issues. What about other eligibility criteria, such as a showing of transportation or financial need, chronic conditions, special services, or safety or treatment compliance?

• *Type of provider offering the transportation.* Should the rules be different depending on the type of provider or supplier offering the transportation services? Free transportation services offered by individuals or small groups of providers, including physicians, or by freestanding clinics have been subject to greater scrutiny. Historically, for example, unscrupulous providers and clinics have offered free transportation in conjunction with Medicare and Medicaid frauds.

• *Destination.* Should a provider be permitted to furnish transportation to other health care providers or only to its own premises for appointments for its own services? Some hospitals apparently provide free transportation to patients for private office visits with local physicians or other professionals; others limit transportation service to practitioners with hospital staff privileges. In addition, many hospitals and physician practices are co-located on a single campus. What safeguards might be included to protect against abuse if transportation is offered to the premises of other providers (*e.g.*, free transportation of patients as a financial benefit to other providers)? What about transportation among entities affiliated through health systems? What about transportation for reasons other than medical appointments?

• *Marketing and advertising.* What are the practical and policy considerations associated with allowing marketing or advertising of complimentary transportation services? What would constitute reasonable limits on promotional activities?

• *Other criteria.* Are there other safeguards, limitations, or conditions that should apply in any exception for complimentary transportation?

2. Clinical Trials

Historically, sponsors of clinical trials have offered various inducements to patients to enroll in their trials. Because Medicare did not cover medical services incident to most clinical trials, these inducements did not trigger scrutiny under the various federal program fraud and abuse sanctions. However, in 2000, the Centers for Medicare and Medicaid Services (CMS) issued a national coverage determination (NCD) providing for coverage for physician, hospital, and other services incidental to certain clinical trials (''Medicare Coverage Routine Costs of Beneficiaries in Clinical Trials''; September 19, 2000). Under the NCD, all other requirements of the Medicare program apply, including the various fraud and abuse authorities. In extending coverage to certain clinical trials, CMS intended to remove impediments to Medicare beneficiaries who want to enroll in trials, but not to grant favored status to clinical trials. This distinction is important, because many clinical trials involve unproven alternatives to existing effective treatments.

Because we are concerned that section 1128A(a)(5) not unduly impede valuable clinical trials, we are soliciting comments and suggestions on how to apply section 1128A(a)(5) to inducements to participate in bona fide clinical trials. Issues of particular interest to the OIG include:

• *Threshold level of Medicare reimbursement.* In many clinical trials, the volume and value of covered Medicare services provided to enrollees is likely to be significant, and trial sponsors may have a financial incentive to offer inducements to Medicare beneficiaries to enroll. For example, hospitalization triggers a substantial Medicare payment. However, it is possible that some clinical trials may involve only a small volume or value of Medicare covered services. Should a possible exception turn on the volume or value of Medicare services involved? If so, what would be the appropriate threshold level?

• *Sponsorship of studies.* One issue in crafting an exception for inducements associated with clinical trials would be defining the universe of trials that would be covered by the exception. We believe covered trials should have a clear potential public benefit. The scope of ''deemed'' trials under the NCD is overly broad for purposes of a possible exception to section 1128A(a)(5) of the Act. We are interested in comments regarding the scope of covered trials and the criteria that might apply to distinguish those with potential public benefit from those with solely or chiefly commercial value. We are also concerned that, as noted in several OIG studies, some trial sponsors provide investigators and other persons in positions to identify and influence potential enrollees with substantial monetary payments. (*See*, for example, the OIG report issued in June 2000, entitled ''Recruiting Human Subjects: Pressures in Industry-Sponsored Clinical Research'' (OEI–01–97–00195)).

• *Type or amount of inducements.* We are interested in information regarding the types of beneficiary inducements that might be offered in connection with clinical trials (*e.g.*, waivers of copayments, provision of otherwise uncovered services, drugs, or equipment). In the clinical trial context,

what are the practical and policy considerations associated with the various forms of inducements? Which kinds of inducements matter most to the efficient and successful completion of a clinical trial? What might be a reasonable cap on the value of inducements offered to particular patients?

• *Sources of benefits.* The OIG is aware that, in some cases, free items or services are offered to enrollees in a clinical trial by parties other than the trial sponsor. For example, a manufacturer might furnish patients with free or discounted products used in the course of the trial (but not the products that are the subject of the clinical trials). These kinds of arrangements raise concerns, as the benefits may induce enrollees to continue to use the manufacturer's products after completion of the trial.

3. Inducements of Low Value

As noted above, Congress indicated an intent to permit items and services of ''nominal'' value under section 1128A(a)(5) of the Act. Consistent with this intent, in the preamble to the final regulations governing section 1128A(a)(5), we indicated that items and services of nominal value are not prohibited by the statute and thus no exception would be necessary (65 FR 24410; April 6, 2000). We further interpreted ''nominal'' value to mean less the $10 per item and $50 in the aggregate on an annual basis (65 FR 24411; April 6, 2000).

We invite comments on whether, for the sake of clarity and bright-line guidance, we should codify an exception for inducements of low value, and, if so, what the value should be. Should the exception include a per item or service limitation on value or should it look solely to value on an annual (or other) aggregate basis?

4. Other Exceptions

The OIG welcomes suggestions for other possible exceptions to section 1128A(a)(5) of the Act. As noted above, comments are particularly useful if they address the legal and policy concerns raised by the application of section 1128A(a)(5) to particular business practices and offer specific suggestions for applicable criteria.

Dated: November 19, 2002.

Janet Rehnquist,

Inspector General.

[FR Doc. 02–31040 Filed 12–6–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

Solicitation of New Safe Harbors and Special Fraud Alerts

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice of intent to develop regulations.

SUMMARY: In accordance with section 205 of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, this annual notice solicits proposals and recommendations for developing new and modifying existing safe harbor provisions under the anti-kickback statute (section 1128B(b) of the Social Security Act), as well as developing new OIG Special Fraud Alerts. In addition, this notice solicits public comments regarding the development of possible guidance addressing certain credentialing practices.

DATES: To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on February 7, 2003.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–71–N, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG–71–N. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, (202) 619–0089, OIG Regulations Officer.

SUPPLEMENTARY INFORMATION:

I. Background

A. The OIG Safe Harbor Provisions

Section 1128B(b) of the Social Security Act (the Act) (42 U.S.C. 1320a–7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward business reimbursable under the Federal health care programs. The offense is classified as a felony and is punishable by fines of up to $25,000 and imprisonment for up to 5 years. The OIG may also propose the imposition of civil money penalties, in accordance with section 1128A(a)(7) of the Act (42 U.S.C. 1320a–7a), or exclusions from the Federal health care programs, in accordance with section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)).

Since the statute on its face is so broad, concern has been expressed for many years that some relatively innocuous commercial arrangements may be subject to criminal prosecution or administrative sanction. In response to the above concern, the Medicare and Medicaid Patient and Program Protection Act of 1987, section 14 of Public Law 100–93, specifically required the development and promulgation of regulations, the so-called ''safe harbor'' provisions, specifying various payment and business practices which, although potentially capable of inducing referrals of business reimbursable under the Federal health care programs, would not be treated as criminal offenses under the anti-kickback statute and would not serve as a basis for administrative sanctions. The OIG safe harbor provisions have been developed ''to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements'' (56 FR 35952; July 29, 1991). Health care providers and others may voluntarily seek to comply with these provisions so that they have the assurance that their business practices are not subject to any enforcement action under the anti-kickback statute or related administrative authorities. The safe harbor provisions are codified at 42 CFR 1001.952.

B. OIG Special Fraud Alerts and Special Advisory Bulletins

The OIG has also periodically issued Special Fraud Alerts and Special Advisory Bulletins to give continuing guidance to health care providers with respect to practices the OIG finds potentially fraudulent or abusive. The Special Fraud Alerts and Bulletins encourage industry compliance by giving providers guidance that can be applied to their own businesses. The OIG Special Fraud Alerts and Bulletins are intended for extensive distribution directly to the health care provider community, as well as those charged with administering the Federal health care programs. The OIG Special Fraud Alerts and Bulletins are available on the